

World Trade Center Health Registry—A Model for a Nanomaterials Exposure Registry

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Objective: To describe the development of and some of the early results from the World Trade Center Health Registry (WTCHR). Is the WTCHR a model for a nanomaterials exposure registry? What lessons may be learned from the WTCHR? **Methods:** We describe the steps involved in creation of the WTCHR, from design through implementation. **Results:** The lessons learned from the WTCHR include thorough documentation of exposure early in the registry, using multimode surveys to maximize response rate, establishing an institutional home with sufficient resources for core as well as in-depth longitudinal and intervention studies, meeting with stakeholders regularly, making data accessible, and timely publication of findings, including wide dissemination of clinical guidelines. **Conclusions:** The process of creating and maintaining the WTCHR provides important lessons for the possible creation of a nanomaterials exposure registry.

The September 11, 2001 (9/11/01), terrorist attack on the World Trade Center (WTC) killed thousands and exposed hundreds of thousands to horrific events resulting from the collapsing towers and immense dust/debris cloud that followed. Types of hazardous chemical exposures associated with this disaster included gypsum, concrete, wood, paper, man-made fibers, chrysotile asbestos (0.8% to 3.0% of mass), quartz, metals, jet fuel, combustion products, diesel exhaust,¹ and aerosols containing sulfuric acid, polycyclic aromatic hydrocarbons, and silicon.² Nanosized particles were likely present, including diesel emissions and ultrafine dust containing carbon nanotubules.³ This article will describe the development of the largest exposure registry for those exposed to the 9/11 disaster and discuss the extent to which this may be an appropriate model for a nanomaterials exposure registry.

CREATING AN EXPOSURE REGISTRY

The WTC Health Registry (WTCHR) is hosted by the New York City (NYC) Department of Health and Mental Hygiene in collaboration with Centers for Disease Control and Prevention (CDC)/Agency for Toxic Substance and Disease Registry (ATSDR)/National Institute for Occupational Safety and Health (NIOSH). With more than 71,000 registrants, it is the largest postdisaster exposure registry in US history.⁴ It was established to prospectively monitor the long-term (20+ yrs) health of workers, residents, and other persons with a high probability of direct exposure to the September 11 terrorist attack and its aftermath.

Establishing an exposure registry of the magnitude of the WTCHR required close coordination between governmental agencies at the local and federal level, multiple institutional review board approvals (CDC, contractor, local health department), timely development of eligibility criteria and questionnaires, extensive outreach and multimodal data collection (phone and in-person interviews and later web and paper surveys).

Discussions about the need to create an exposure registry for those exposed to the WTC disaster began within a few weeks after 9/11/01. The magnitude of the exposure to both physical and stress-related risk factors and the large estimated eligible population⁴ ($N = 410,000$) were factors in the decision-making process. The NYC Commissioner of Health believed that a 9/11 registry would protect impacted people from being repeatedly being sought out by researchers for different studies, and at the same time, encourage legitimate research, serve a public health purpose, be comprehensive, and include all those exposed and willing to participate. A scientific advisory committee (SAC) first met in February 2002, including representatives of the local health department, academic institutions, clinical groups, and relevant Federal agencies. The decision to create an exposure registry was made by NYC Department of Health and Mental Hygiene in conjunction with representatives from the CDC, including NIOSH and the National Center for Injury Prevention and Control.

A few weeks after 9/11/01, a CDC assignee was designated as lead scientist responsible for drafting an initial protocol. Changing the health code to require participation was considered, but a decision was made to make it a voluntary registry, largely due to concerns that a health code amendment might delay the initiation of the registry and difficulty determining which geographically diverse groups or individuals might be required to register. The study protocol was modeled the basis of the registry created after the Oklahoma City bombing of 1996, as well as the ATSDR's National Environmental Registry, a voluntary registry of persons exposed to contaminated water supplies or exposure to dioxins and other chemicals. The registry was determined to be "research" rather than "public health surveillance". The specific aims included the following: (1) expand knowledge about the long-term health effects of the 9/11 disaster; (2) conduct community activities to respond to the health concerns and specific needs of enrollees and others exposed to 9/11; (3) maintain the registry as a valuable public health resource for future research.

The initial WTCHR protocol included sections on identifying target populations, methods of recruitment and enrollment, data collection instrument development, data collection, management of psychological distress, training of personnel conducting the survey, informed consent, tracking registrants over time, information management, data analysis, roles and responsibilities of investigators, oversight of the registry, and constitution of the SAC. The first SAC meeting occurred in February 2002. The study protocol was delivered to the director of the CDC by the NYC Commissioner of Health. Evaluation of potential chronic physical as well as mental health effects, cancer, and mortality, was planned from the beginning of the WTCHR.

In July 2002, ATSDR announced a \$20 million award for establishment of the registry authorized by the Federal Emergency Management Agency. The ATSDR was identified as the lead Federal agency through which funding would be managed. Subsequent funding, including several million dollars per year for the analysis of the Wave 1 survey, creation of a Wave 2 survey (2006 to 2008), and ongoing maintenance of the WTCHR, was obtained from the Environmental Protection Agency and the ATSDR. The NYC provided additional funding for an in-depth respiratory study of residents and area workers, and preparation for future cancer and mortality studies. Future funding for maintaining the WTCHR is scheduled to

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The primary focus of recruitment in the beginning was through requesting lists of potentially exposed employees, residents, or persons with security badges for the damaged and destroyed buildings, for example, a Port Authority listing of over 90,000 badge holders. Over 200 key employers, unions, and agencies provided lists, or access via E-mail to their respective populations. Innovative recruitment efforts were required to reach specific target populations, including extensive use of the media, point of purchase stands with flyers, door-to-door recruitment, attendance at police department roll calls and visits to fire houses throughout NYC.

Three separate institutional review board applications were submitted. One, for the NYC Department of Health, one for the CDC, and one for Research Triangle Institute, the contractor engaged to conduct the Wave 1 interview survey. The three institutional review board approvals took more than 1 year from original date of submission.

Enrollment interviews were conducted from September 2003 through November 2004 yielding 71,437 enrollees from all 50 states.⁵ Eligibility groups included persons most likely to have had direct exposure to the events of 9/11. Persons who were present in lower Manhattan south of Chambers Street ($n = 43,487$), rescue and recovery workers and volunteers who worked at least one shift on the WTC site ($n = 30,665$), residents of Lower Manhattan south of Canal Street ($n = 14,665$), and Lower Manhattan school students ($n = 2,075$) and school staff ($n = 571$).

In addition to the SAC created during the initial phase of the WTCHR, a community advisory board and later a labor advisory committee were created to ensure that input from community and labor groups and communication of the registry findings would be achieved throughout the remaining life of the registry.

One of the primary tasks of the registry was to document the extent of self-reported exposure of registrants to the events of 9/11/01. Determinants of exposure considered in developing the Wave 1 WTCHR survey include

- dust cloud exposure, home and workplace dust exposure
- proximity to WTC site or occupant of collapsed or damaged buildings
- atmospheric dispersion patterns and building canyon effect
- history of injury on 9/11/01
- reported witnessing of horrific events on 9/11/01
- onset and duration of exposure
 - rescue and recovery workers
 - location of work and specific tasks performed on 9/11, 9/12, 9/13–17, 9/18–12/31/01, and 1/1/02–6/30/02
 - no. of days worked at WTC site, no. of hours/day, and use and adequacy of respiratory protection
 - residents, area workers, and students
 - evacuation, date of return, condition of buildings, thickness of settled dust, methods and timing of cleaning, and adequacy of cleaning
 - passersby
 - location, time of exposure to dust cloud.

CLARIFYING EXPOSURE, SOCIAL SUPPORT, AND IMPACT OF 9/11 ON OVERALL HEALTH AND DISABILITY—THE WAVE 2 SURVEY, 2006 to 2008

The WTCHR was designed to conduct periodic surveys of registrants. To this end, a second health survey was conducted 2006–2008.⁶ This survey gathered self-reported information from registrants on medical disease diagnoses, self-reported cancer incidence, and chronic mental health effects including psychological distress as

well as diagnosed Posttraumatic Stress Disorder (PTSD), depression, and anxiety.

The 30-minute Wave 1 survey did not allow for sufficient details on exposure in three following main areas that were added to the Wave 2 survey: (1) mask and respirator type and use, training, and cleaning; (2) condition of residence, details on evacuation and residential cleanup; and (3) condition of workplace for area workers who returned after evacuation. The Wave 2 survey also asked questions regarding social support, unmet health care needs, and general health and disability. The Wave 2 survey benefited from extensive input from the WTCHR's SAC, community advisory board, and labor advisory committee.

MAINTAINING AN EXPOSURE REGISTRY

Much of the work in maintaining an exposure registry involved contacting registrants with information and requests for updated contact information, and offering assistance with locating services and referrals. The WTCHR maintains regular contact through an annual report of findings, an annual card, a frequently updated Web site (<http://nyc.gov/html/doh/wtc/html/registry/registry.shtml>), and specific mailings with resource guides, clinical guidelines, and invitations to forums or other presentations regarding the registry.

On the Wave 2 survey, registrants reported unmet health care needs, including both physical and mental health needs. Individualized follow-up has been undertaken, starting with residents, area workers, and passersby, to insure that each registrant with PTSD and/or reported physical health problems is referred to appropriate care. Customization and personalization of the outreach letters was important to improve the response rate to this intervention.

To achieve the first goal of the registry, expanding knowledge about the long-term health effects of the 9/11 disaster, periodic surveys of registrants have been conducted, to update health information and monitor potential health effects and health needs. In addition, the registry conducts mortality and cancer studies, matching registrant data with the National Death Index and state cancer registries. In the future, surveillance for chronic health effects such as cardiovascular diseases or other illnesses that likely involve hospitalizations will include matching with hospital registries.

Adverse respiratory health effects from 9/11 reported by the WTCHR have included increased incidence of asthma⁷ and increased symptoms of cough, wheezing, and shortness of breath^{5,6} associated with increased exposure on and after 9/11/01. Registry research is also informed by other 9/11-related research, for example, reports of significant declines in forced expiratory volume in 1 second and forced vital capacity^{8–10}; increased symptoms of cough, wheezing, chest pain, and shortness of breath^{9–11}; case reports of acute eosinophilic pneumonia¹² and sarcoid-like granulomatous lung disease.¹³ Carbon nanotubes have been found in lung biopsies of WTC-exposed workers with interstitial lung disease.³ Other nonrespiratory adverse physical health effects have been reported, including increased gastroesophageal reflux disease,^{14,15} sinusitis,¹⁵ and vocal cord dysfunction.¹⁶

Mental health consequences reported among WTCHR registrants after exposure to the disaster have included PTSD symptoms and diagnosed PTSD, depression, and anxiety.^{17–20}

A LONG-TERM PERSPECTIVE

Follow-up surveys of WTCHR registrants are planned every 3 to 4 years, until at least 20 years have elapsed from the date of enrollment. Assessing the long-term consequences of a large environmental disaster of this type requires ongoing commitment of funding agencies, governmental agencies, and advisors to sustain core research (eg, periodic surveys), as well as core communication and tracing activities to maintain an updated and engaged cohort. The WTCHR informs registrants, the public, and policy makers

about the health impacts of 9/11 through peer-review publications, clinical guidelines, and a dedicated Web site.

LIMITATIONS

The voluntary nature of the WTCHR means that some populations may have been underrepresented and selection bias may influence some of the results. We did recruit from over 200 lists of those most likely exposed to the events associated with 9/11 and have adjusted for source of enrollment in many WTCHR analyses. The lack of objective exposure data, particularly during the first week after the disaster, and the self-reported nature of WTCHR exposure and most health outcome data (except for mortality and cancer) means that over- or under-reporting may have occurred. Recall bias may have been present because the Wave 1 survey was conducted several years after the events of 9/11/01. We are currently conducting validation studies of selected health outcomes (eg, sarcoidosis, self-reported cancers) to address possible over- or under-reporting. Since WTCHR surveys have been conducted using multiple modes (paper, web, and computer-aided telephone or in-person interviews), registry analyses have had to address potential mode effects.

IN WHAT WAYS IS THE WTCHR A POTENTIAL MODEL FOR A NANOMATERIALS EXPOSURE REGISTRY?

The WTCHR has several characteristics that make it an appropriate model for a nanomaterials exposure registry, including its large size, focus on a relatively unique set of exposures, national scope with regional emphasis, planning for long-term follow-up of diverse health outcomes, provision for external research collaboration, public use data sets, and multiple sources of funding.

The lessons learned from the WTCHR that might apply to a nanomaterials registry include documenting potential exposure hazard and actual exposure levels, as thoroughly as possible early in the registry, and addressing physical as well as mental health issues, although for a nanomaterials registry, neuropsychological and neurobehavioral issues will likely be important to measure as well. Although multimode surveys may be needed to maximize response rate and enrollment in a nanomaterials registry, potential mode effects may need to be addressed in the analysis of the data.

The WTCHR has found that one key to the successful retention of registrants is the timely release of findings through publications. In addition, regular communications, maintaining an up-to-date dedicated Web site, and insuring transparency through timely and regular communications with labor and community advisory committees have all contributed to the high retention rate (only several hundred registrants had withdrawn from the WTCHR by the end of 2010). Similarly, keeping results accessible through public access databases, with an easy-to-use interactive Web application has facilitated involving the broader scientific community, media, and the public in a better understanding of the data. The WTCHR, in response to public and medical community needs, has translated scientific findings into clinical guidelines, with updates as the science develops.

It is essential to establish an exposure registry of this magnitude within an institutional home with adequate resources for core funding for periodic surveys and maintaining contact with enrollees. Additional dedicated funding has been needed to support ancillary longitudinal in-depth studies and interventions to respond to enrollee concerns.

Finally, recognizing the complexity of the exposure and outcome measures used in a large and diverse registry such as the WTCHR, it has been important to collaborate and coordinate with other researchers: Establishing effective means of communication and coordination of methods from the beginning of an exposure

registry will improve comparability of analyses. Consistent reports of findings between researchers will strengthen the potential impact of the registry findings on policy.

CONCLUSION

As the WTCHR approaches the 10th anniversary of the 9/11/01 disaster, it can serve as a potential model for future exposure registries, not just for tracking the long-term health effects of environmental disasters such as the Gulf of Mexico oil spill of 2010, but also making possible early and ongoing documentation of effects of exposure to workers engaged in emerging technologies, such as the nanomaterials industry. Establishing such an effective exposure recording and health tracking system will ensure that the health of workers is being effectively protected, and reassure the public that such technologies live up to their promise of progress and innovation without undue health risks.

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